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SangStat Announces Agreement with Eli Lilly for Manufacturing of CYCLOSPORINE; SangStat Retains Worldwide Commercial Rights

Business Wire, Nov 6, 1996

MENLO PARK, Calif.--(BUSINESS WIRE)--Nov. 6, 1996--SangStat, The Transplant Company (Nasdaq: SANG) announced today that Eli Lilly and Company has agreed to manufacture the finished commercial supply of SangStat's proprietary CYCLOSPORINE product candidate for the anticipated worldwide market.

SangStat retains the exclusive commercial rights worldwide.

SangStat has spent several years developing its proprietary CYCLOSPORINE formulation and chose Eli Lilly, a well established, leading U.S. pharmaceutical company with affiliates worldwide, as the preferred manufacturer of the finished product. Eli Lilly will fill and finish bulk CYCLOSPORINE, provided by SangStat, for subsequent commercial sale and distribution worldwide by SangStat.

"Eli Lilly had the necessary manufacturing facilities, expertise and production capacity we were looking for to meet SangStat's expected CYCLOSPORINE finished product requirements," said Ralph Levy, Senior V.P. Operations.

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Eli Lilly manufactured the exhibit batches used in SangStat's pivotal CYCLOSPORINE bioequivalence trials. The results of these trials demonstrated that SangStat's CYCLOSPORINE formulation was clearly bioequivalent to branded cyclosporine, a requirement for FDA approval as a generic drug.

Based on these results, SangStat intends to file an Abbreviated Antibiotic Drug Application (AADA) for marketing clearance with the FDA by year end.

"We are very pleased that Eli Lilly has agreed to be our CYCLOSPORINE finished product manufacturer," said Philippe Pouletty, M.D., Chairman and CEO. "Lilly's excellent reputation in pharmaceutical manufacturing offers the transplant community a name they can trust for this lifesaving medication."

Cyclosporine is the leading immunosuppressive drug used in transplantation to prevent graft rejection. It is currently marketed by Sandoz Ltd. in different formulations with 1995 worldwide sales reported at \$1.2 billion.

In the United States and Europe there are more than 200,000 transplant recipients requiring daily immunosuppressive therapy for the rest of their lives, the majority of whom take cyclosporine.

SangStat is a biopharmaceutical company applying a disease management approach to improve the outcome of organ transplantation. The Company has a total of 12 monitoring and therapeutic product and product candidates to address the pre-transplant, acute care and chronic phases of transplantation.

Products in development include THYMOGLOBULIN(R) (exclusive marketing and development rights from Pasteur Merieux Serums et Vaccins "PMsv" for the U.S. and Canada) to treat graft rejection, CYCLOSPORINE and AZATHIOPRINE for chronic immunosuppressive therapy and ALLOTRAP(R) 2702 to promote graft acceptance following transplantation.

Monitoring products include PRA-STAT(R) and CROSS-STAT(R) (both marketed in the U.S. and Europe), and product candidate TYP-STAT(TM), all designed to improve donor/recipient compatibility. Other monitoring products in development are intended to guide post-transplant therapy; CELSIOR(R) (exclusively licensed from PMsv) is an organ preservation solution; and drug candidate XE-9 is in early development for xenotransplantation.

XENOJECT(TM) platform technology also is in the discovery phase for replacing antibody therapy with small

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SangStat is located in Menlo Park, and operates The Transplant Pharmacy(TM), a comprehensive pharmacotherapy management program, and wholly-owned subsidiaries, XenoStat, Inc., in Menlo Park, SangStat Atlantique S.A. in Nantes, France and SangStat Canada, Ltd. in Mississauga, Ontario, Canada.

This press release contains forward-looking statements that involve risks and uncertainties. The Company's actual results may differ significantly from the results discussed in the forward-looking statements.

Factors that might cause such a difference include, but are not limited to, those risks associated the company's ability to obtain regulatory approval for its CYCLOSPORINE, manufacturing of commercial quantities of CYCLOSPORINE on commercially favorable terms and the like.

For a discussion of factors that might result in different outcomes, see the section under the caption "Risk Factors" beginning on page 30 of the 1995 Annual Report to Stockholders.

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EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	5	514/2.ccls. and (cyclosporin or cyclosporine or ciclosporin or ciclosporine) SAME (extraction or feedstock or fractional)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 06:58
L2	908	(cyclosporin or cyclosporine or ciclosporin or ciclosporine) and (heptane or n-heptane)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 06:59
L3	28	(cyclosporin or cyclosporine or ciclosporin or ciclosporine) SAME (heptane or n-heptane)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 06:59
L4	6	(cyclosporin or cyclosporine or ciclosporin or ciclosporine) SAME n-heptane	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 07:00
L5	101	(cyclosporin or cyclosporine or ciclosporin or ciclosporine) and n-heptane	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 07:00
L6	41	(cyclosporin or cyclosporine or ciclosporin or ciclosporine) and n-heptane SAME (acetone or isopropanol)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 07:02
L7	19	(cyclosporin or cyclosporine or ciclosporin or ciclosporine) and n-heptane SAME (acetone or isopropanol) and bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 07:01
S1	31	(cyclosporin or cyclosporine) SAME bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 19:12
S2	10	(cyclosporin or cyclosporine) SAME bulk SAME (purity or impurity or HPLC or pure or impure)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 19:15

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S3	21	(cyclosporin or cyclosporine) SAME bulk and (purity or impurity or HPLC or pure or impure)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 19:15
S4	0	("5686133".did. or "5834022".did. or "5851275".did.) and (cyclosporin or cyclosporine) SAME bulk and (purity or impurity or HPLC or pure or impure)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 19:16
S5	3	("5686133".did. or "5834022".did. or "5851275".did.) and (cyclosporin or cyclosporine) SAME bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 19:26
S6	3	("5686133".did. or "5834022".did. or "5851275".did.) and (cyclosporin or cyclosporine) SAME (bulk or kg)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 19:27
S7	0	("5686133".did. or "5834022".did. or "5851275".did.) and (cyclosporin or cyclosporine) SAME kg	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 19:27
S8	0	("5686133".did. or "5834022".did. or "5851275".did.) and (cyclosporin or cyclosporine) and kg	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 19:27
S9	1271	(cyclosporin or cyclosporine) SAME kg	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 19:27
S10	136	(cyclosporin or cyclosporine) SAME kg and bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 19:28
S11	4	(cyclosporin or cyclosporine) SAME kg SAME bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 19:27
S12	89	(cyclosporin or cyclosporine) SAME kg and bulk and (HPLC or purity or impurity or pure or impure)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 19:28

EAST Search History

S13	17	(cyclosporin or cyclosporine) SAME kg and bulk SAME (HPLC or purity or impurity or pure or impure)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 19:29
S14	44	(cyclosporin or cyclosporine) SAME kg SAME (HPLC or purity or impurity or pure or impure)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 20:29
S15	24	(cyclosporin or cyclosporine) SAME kg SAME (HPLC or purity or impurity or pure or impure) and (cyclosporin or cyclosporine).ab.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 19:30
S16	1885	(cyclosporin or cyclosporine) SAME ("99" or "99.5" or pure or "100")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 20:30
S17	1778	(cyclosporin or cyclosporine) SAME ("99" or "99.5" or "100")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 20:30
S18	310	(cyclosporin or cyclosporine) SAME ("99%" or "99.5%" or "100%")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 20:30
S19	36	(cyclosporin or cyclosporine) SAME ("99.5%")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 20:30
S20	18	(cyclosporin or cyclosporine) SAME ("99.5%") and bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 20:31
S21	4	(cyclosporin or cyclosporine) SAME ("99.5%") SAME bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 20:30
S22	4	(cyclosporin or cyclosporine) SAME ("99.5%") SAME HPLC	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 20:31

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S23	29	(cyclosporin or cyclosporine) SAME ("99.5%") and HPLC	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 20:34
S24	3	(cyclosporin or cyclosporine) SAME "100%" SAME (purity or impurity or pure or impure)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 20:40
S25	14	(cyclosporin or cyclosporine) SAME pure SAME (kg or bulk)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 20:41
S26	51	(cyclosporin or cyclosporine) SAME pure and (cyclosporin or cyclosporine) SAME (kg or bulk)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 21:17
S27	38	(cyclosporin or cyclosporine) SAME ("1 kg" or bulk)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/10/31 21:18
S28	11	(cyclosporin or cyclosporine) SAME ("1 kg")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:25
S29	4	(cyclosporin or cyclosporine) SAME kg SAME bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:25
S30	8	(cyclosporin or cyclosporine) SAME kg and (cyclosporin or cyclosporine) SAME bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:26
S31	31	(cyclosporin or cyclosporine) SAME bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:38
S32	13	(cyclosporin or cyclosporine) SAME bulk and kg	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:27

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S33	136	(cyclosporin or cyclosporine) SAME kg and bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:27
S34	14	(cyclosporin or cyclosporine) SAME kg and bulk and (cyclosporin or cyclosporine).ab.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:28
S35	0	(cyclosporin or cyclosporine) SAME "HSCCC"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:28
S36	46	"HSCCC"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:28
S37	8	"HSCCC".ab.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:28
S39	0	(cyclosporin or cyclosporine) and "HSCCC"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:31
S40	0	"20040040782".did. and "HSCCC"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:31
S41	31	(cyclosporin or cyclosporine) SAME bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:39
S42	1395	(cyclosporin or cyclosporine) and bulk and (extraction or feedstock or fractional)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:39
S43	971	(cyclosporin or cyclosporine) and kg and bulk and (extraction or feedstock or fractional)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:39

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S44	109	(cyclosporin or cyclosporine) and kg and bulk and extraction and (feedstock or fractional)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:40
S45	7	(cyclosporin or cyclosporine) and kg and bulk and extraction and feedstock and fractional	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:39
S46	4	(cyclosporin or cyclosporine) SAME bulk and kg and extraction and (feedstock or fractional)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:50
S47	6	(cyclosporin or cyclosporine) and kg and bulk and extraction and (feedstock or fractional) and (cyclosporin or cyclosporine).ab.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:41
S48	313	(cyclosporin or cyclosporine) SAME kg and (extraction or feedstock or fractional)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:50
S49	10	(cyclosporin or cyclosporine) SAME kg SAME (extraction or feedstock or fractional)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:42
S50	14	(cyclosporin or cyclosporine or CsA) SAME kg SAME (extraction or feedstock or fractional)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:42
S51	285	(cyclosporin or cyclosporine or CsA) SAME (extraction or feedstock or fractional)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:42
S52	35	(cyclosporin or cyclosporine or CsA) SAME (extraction or feedstock or fractional) and bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:47
S53	1399	(cyclosporin or cyclosporine or CsA) and bulk and processing and kg	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:48

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S54	0	immunosuppressive SAME bulk SAME kg	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:49
S55	11	immunosuppressive SAME bulk and kg	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:49
S56	74	immunosuppressive SAME kg and bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:49
S57	3927	(cyclosporin or cyclosporine) and kg and (extraction or feedstock or fractional)"ab."	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 05:08
S58	0	(cyclosporin or cyclosporine) and kg and (extraction SAME feedstock SAME fractional).ab.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:50
S59	26	(cyclosporin or cyclosporine) and kg and (extraction or feedstock or fractional).ab.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:52
S60	39	(cyclosporin or cyclosporine or CsA or ciclosporin or ciclosporine) and kg and (extraction or feedstock or fractional).ab.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:55
S61	382	(cyclosporin or cyclosporine or CsA or ciclosporin or ciclosporine) and (industrial or commercial) SAME processing	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:55
S62	263	(cyclosporin or cyclosporine or ciclosporin or ciclosporine) and (industrial or commercial) SAME processing	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:55
S63	9	(cyclosporin or cyclosporine or ciclosporin or ciclosporine) SAME (industrial or commercial) SAME processing	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:56

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S64	1	(cyclosporin or cyclosporine or ciclosporin or ciclosporine) and ((industrial or commercial) SAME processing).ab.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:56
S65	109	(cyclosporin or cyclosporine or ciclosporin or ciclosporine) and bulk SAME processing	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:57
S66	0	(cyclosporin or cyclosporine or ciclosporin or ciclosporine) and bulk SAME processing SAME kg	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:57
S67	1	(cyclosporin or cyclosporine or ciclosporin or ciclosporine).ab. and bulk SAME processing	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:57
S68	9	(cyclosporin or cyclosporine or ciclosporin or ciclosporine).clm. and bulk SAME processing	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 04:57
S69	182	(cyclosporin or cyclosporine or ciclosporin or ciclosporine) SAME (extraction or feedstock or fractional)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 06:58
S70	12	bulk SAME (cyclosporin or cyclosporine or ciclosporin or ciclosporine) and (extraction or feedstock or fractional)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 05:49
S71	0	("5382655".did. or "5767069".did. or "6255100".did.) and bulk SAME (cyclosporin or cyclosporine or ciclosporin or ciclosporine) and (extraction or feedstock or fractional)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 05:49
S72	5	("5382655".did. or "5767069".did. or "6255100".did.)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 05:51

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S73	0	("5382655".did. or "5767069".did. or "6255100".did.) and bulk	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 05:51
S74	3	("5382655".did. or "5767069".did. or "6255100".did.) and kg	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2006/11/01 05:51